

**REMARKS**

Reconsideration is respectfully requested in view of the above amendments and the following remarks. Applicants seek to amend claim 19 to put the case in better form for appeal. The amendment is fully supported throughout the specification as filed. Accordingly, no new matter has been added. After entry of the present Amendment, claims 19-24 and 34-42 will be under consideration.

Applicants respectfully bring to the Examiner's attention an apparent error on page 1 of the Office Action pertaining to claims 34, 36-39, 41, and 42 being withdrawn from consideration. Upon review of the prosecution history, Applicants have found that claims 1-18 and 33 were cancelled in a Preliminary Amendment filed October 4, 2000, and that claims 25-32 were cancelled in an Amendment filed November 19, 2002. A record of claims 34, 36-39, 41, and 42 being cancelled was not discovered. Thus, Applicants will assume that claims 19-24 and 34-42 are pending in the application at the time of this Office Action, and request correction if this is incorrect.

**CLAIM REJECTIONS UNDER 35 U.S.C. § 102(b)****Claims 19-24, and 34-42 in view of WO 95/05416**

Claims 19-24 and 34-42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by WO 95/05416 (WO '416). The Examiner states that WO '416 teaches treatment of a mucosal surface with a composition comprising an adhesive layer and other layers which are water-soluble and contain an active. Furthermore, the Examiner asserts that plasticizers are optional rather than required in WO '416 because plasticizers are not mentioned in the section entitled "summary of the invention" (page 5 line 4-page 11 line 23), independent claims 9 and 19 and their dependent claims do not include plasticizer as a limitation, Example III (page 32) does not disclose a plasticizer, and in the section entitled "disclosure of the invention" on page 11 lines

27-31, plasticizers are disclosed as an embodiment rather than a requirement by the preamble "In one general aspect," (underlining added for emphasis).

Applicants submit that WO '416 is distinguished by the present amendment to claim 19. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See MPEP § 2131 (citing *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)). Claim 19 has been amended to recite that the adherent film that is free of plasticizer and applied at the mucosal treatment site is also flexible. Support for this amendment is found at page 22, lines 21-23, and in Example 37 on page 35 of the specification. In WO '416, films made without a plasticizer, e.g., as noted in Example III, are described as inflexible. WO '416 states on page 21, lines 3-7:

"Suitable slow-dissolving polymers such as HPC are typically not sufficiently flexible to conform with the irregularly curved surfaces of the oral cavity or of oral or dental prostheses, and addition of a plasticizer to the polymer or polymer mixture of films would be required for these applications."

In other words, an inflexible film that is unable to conform to a mucosal surface would have insufficient contact with that surface to adhere properly. Without the ability to stick, the film would be ineffective for its intended use. Therefore, because WO '416 teaches that layered films made without plasticizer are inflexible, they clearly wouldn't be able to conform to a mucosal surface such that it is protected and treated, as required by amended claim 19.

In view of the above, Applicants submit that amended claim 19 and the claims depending therefrom are novel over WO '416 under 35 U.S.C. § 102(b) and request withdrawal of the rejection.

**SUMMARY**

Applicants have by way of the amendments and remarks presented herein, made a sincere effort to overcome the rejections and address all issues that were raised in this Final Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 359872000810. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: April 25, 2003

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